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ANDA Litigation Intelligence Report

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Prepared By

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A comprehensive report on the top 100 best performing and most active Hatch-Waxman attorneys and law firms.

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Introduction

Decision making is difficult when facts are missing. But, once all the facts and data are available, it will become a conclusion rather than a decision. With advances in computing power and artificial intelligence, processing large amounts of data is now possible. This has enabled corporate executives in many segments of the economy to make faster and more informed decisions, which has resulted in increased productivity.

The legal sector is not excluded. We published our first *IP Intelligence Report*, covering all Inter-Partes Reviews (IPR) almost three years ago (September 2017). Since then, we have expanded our offerings to also include *Patent Prosecution, ITC Section 337* and now, for the first time, this *Abbreviated New Drug Application (ANDA) Intelligence Report* that you are holding (digitally).

Companies regularly use our IP reports when struggling to select the right counsel for various IP related matters. The positive feedback from our past reports prompted us to expand that effort and cover one of the very important categories of IP litigation concerning both generic and brand pharmaceutical companies (*Hatch-Wax-man Act*).

After we published our ITC Intelligence Report in January, we looked at several new areas including trademark, ANDA litigation and patent litigation in both Federal and District Courts. Although the Hatch-Waxman and ANDA community is relatively small compared to other IP areas, its impact is big. It took us about six months, and a team of computer scientists and data analysts, to gather, sort, and cluster the data before we could extract meaningful insights from it. We faced many obstacles throughout this project.

Most of the ANDA cases have numerous documents that are written in different formats and do not necessarily follow any standard guidelines, many of which need to be reviewed manually. To calculate and allocate winning points for different stakeholders, we were forced to manually review hundreds of documents to insure high quality and accuracy.

After our initial review of ANDA cases, we identified 1,105 attorneys involved in a total of 976 ANDA cases filed in a 3 year period between June 1, 2017 and June 1, 2020. The majority of the cases were filed in New Jersey and Delaware district courts. As a result, some Delaware or New Jersey counsel played an important role as they worked

with various pharmaceutical companies to represent them locally in New Jersey or Delaware district courts. We decided to dedicate a complete section to local counsel and identify the most active attorneys who acted as local counsel in different states. Identifying these attorneys was not easy and this added to the complexity of the report. While we are not claiming 100% accuracy, we certainly hope we can get there over time.

I would also like to thank our dear attorneys and IP community who provided their time and helped us by clarifying some of the doubts we had for performance measurement of special cases which were not obvious to us. They carefully answered and reasoned why we should consider one outcome over another (Patexia Insight ANDA Survey published in July 2020).

In addition, with the new upgrade, Patexia's website now allows all IP attorneys to directly review and verify their cases through their profile pages. We contacted all ANDA attorneys as well as local counsel, and provided them with a unique link to their cases. Many spent time and reviewed their cases which added another layer of confidence to our process, and helped us ensure higher accuracy for our analysis.

We plan to further expand our IP Intelligence offerings in 2020 by providing one new report to cover the top trademark attorneys all over the country. All these reports will automatically become available to our <u>Concierge Members</u>.

We hope our IP community finds this extensive information useful when making critical day to day decisions about their legal partners.

Pedrom Samen

PEDRAM SAMENIFounder and CEO



What's in This Report?

The report content has been divided into the following sections:

- Ranking Methodology: We explain our performance model and how we calculated the Activity, Success, and Performance scores and rankings for plaintiffs, defendants, their representatives, and ANDA judges.
- Hours and Costs: For the first time in one of our Intelligence Reports, we present typical hours, costs, and staffing for ANDA cases, based on community feedback.
- 3. ANDA Statistics: We provide a 360-degree overview of ANDA from 10,000 feet. We cover high-level statistics about ANDA, including all parties, judges and cases, covering June 1, 2017 June 1, 2020.
- **4. Plaintiffs and Defendants:** We identify the most active and the best-performing *Plaintiffs and Defendants* over the period of our study.

- 5. ANDA Firms: We analyze the performance and activity of law firms, comparing and providing rankings for the top firms representing *Plaintiffs and Defendants*.
- **6. ANDA Attorneys:** We review the performance and activity of ANDA attorneys, representing *Plaintiffs and Defendants*, comparing and providing rankings for top attorneys on each side.
- 7. Local Counsel: We review and identify the most active local counsel, representing Plaintiffs and Defendants, comparing and providing rankings for top attorneys on each side.
- **8. ANDA Judges:** We look at the judges assigned to all ANDA cases for the period of this study and calculate their performance based on the outcome of their judgments.

As per our tradition for this and our other intelligence reports, and to have a meaning-ful comparison, as well as compensating for the time required for each case from filing to completion (e.g., 6 to 36+ months), we covered a period of three years, June 1, 2017 through June 1, 2020. Appendix A lists all sources of data used for this report.

DISCLAIMER: The data for this report was obtained from public sources including USPTO, PTAB, and PACER, as well as self-reported by attorneys on the Patexia website. Patexia has gone to great lengths to provide valid and accurate analysis based on this data. However, Patexia does not guarantee 100 percent accuracy nor takes any responsibility for possible losses caused by the use of any information provided in this report.

Executive Summary

In the 976 ANDA cases filed from June 1, 2017 to June 1, 2020, ninety-seven (97) judges, 319 companies, 867 ANDA attorneys, 250 local counsel and 140 law firms participated. Out of 319 pharmaceutical companies, 182 companies were named as plaintiffs, while 180 were named as defendants.

Our activity scores and rankings were developed based on all 976 cases, whereas the 551 of these 976 cases that terminated during this same period were the basis for our success and performance scores. As with previous reports, we will be providing law firm and attorney participants with the most active and best performing ANDA badges for 2020.

Year-over-year ANDA activity declined from 30.4 cases/month filed in 2017, to 22.6/month in 2020. This is in-line with the larger trend we had observed in patent litigation in recent years (i.e., similar patterns were seen in district courts, IPR, and ITC). Although early data from the first half of 2020 indicate that patent litigation may be poised for a rise again.

A total of 959 unique patents were at the center of these 976 ANDA cases. Analyzing these patents by International Patent Classification (IPC) revealed a total of 55 different IPC codes. As expected, 871 or 89 percent of patents were classified under IPC code A61K, which relates to the preparation of

pharmaceuticals. The other identified IPC codes also relate to the composition, preparation, manufacture, preservation, or delivery of chemicals, pharmaceuticals, therapeutics, or medicinals.

Teva Pharmaceutical was the most active company overall, with a total of 108 cases, and Finnegan, Henderson, Farabow, Garrett & Dunner LLP was the most active law firm overall with a total of 89 cases.

Data suggests that a small group of law firms have a very strong relationship with large pharmaceutical companies on the brand side and manage to represent them in the majority of their cases, while generic pharmaceutical companies work with a more diverse set of law firms.

There are several newly formed firms that have gained momentum and are working with large pharmaceutical companies despite their relatively small size and young age.

97 judges participated in a total of 976 ANDA cases. A total of 551 cases have been concluded with mean, min, and max case loads of 14.2, 1, and 168 respectively for all judges. Min, max, and average Judge scores, reflecting the likelihood of decision favoring the Plaintiff (Brand) in adjudicated cases, were 0, 1, and 0.79 respectively, which means the likelihood of victory for the brand side is 79%.



Appendix A

Sources of Data

Data is the foundation and building block of any data-driven analysis. Therefore, collecting that data from quality sources, and taking extra care in maintaining the data's integrity, is something that we, at Patexia, take very seriously. We have collected our raw data from many sources including:

- Public Access to Court Electronic Records (PACER)
- Patent Trial and Appeal Board (PTAB)
 Database
- United States Patent and Trademark (USPTO) Patent Database
- US Patent Classification Database
- Self-reported by attorneys named on the case

For this release, we limited the date range of our analysis to the last three years (June 1, 2017 through June 1, 2020).

While the possibility of errors such as typos in legal documents are inevitable, cleaning

and organizing the attorney data is even more challenging as attorneys change firms, may not update their information, and often use different variations of their names.

Our engineering team has implemented sophisticated machine learning and natural language processing techniques to find the correct matches for various occurrences of the same name. To further minimize the errors, we not only review suspicious matches manually, but also host profile pages for more than 80,000 attorneys and agents who can directly review and add missing cases to our database.

We contacted more than 800 ANDA attorneys and requested that they review their cases for accuracy. All the user-added data was again verified by Patexia's internal data team for accuracy.

Appendix B

List of All ANDA Cases

See the attached Excel file for the list of all 976 ANDA cases filed from June 1, 2017 through June 1, 2020. The spreadsheet covers the following information for each case:

 Case Number with a link to the case page on Patexia site

- · Case Filing Date
- Case Decision Date (if terminated)
- Status
- Judge
- Court
- Case Title
- Conclusion (if case terminated)

Appendix C

Brand and Generic Pharmaceuticals

See the attached Excel file for the stats related to all 319 pharmaceutical companies involved in one or more ANDA/Hatch-Waxman cases, filed during the period of our study. The spreadsheet covers the following information for each of the companies:

- Company name with a link to Patexia page
- All Cases: Total number of ANDA cases for the period
- Defendant Cases
- Plaintiff Cases
- Overall Activity Rank

- Overall Performance Rank
- Defendant Activity Rank
- Defendant Performance Rank
- Plaintiff Activity Rank
- Plaintiff Performance Rank
- Overall Success Rank
- Defendant Success Rank
- Plaintiff Success Rank
- Overall Success Score
- Defendant Success Score
- Plaintiff Success Score
- Overall Performance Score
- Defendant Performance Score
- Plaintiff Performance Score

Appendix D

Stats for ANDA Firms

See the attached Excel file for the stats related to all 139 law firms, involved in one or more ANDA cases. The list does not include firms that we identified as local counsel. The spreadsheet covers the following information for each of the law firms:

- Law firm name with a link to Patexia page
- All Cases: Total number of ANDA cases for the period
- Defendant Cases
- Plaintiff Cases
- Overall Activity Rank

- Overall Performance Rank
- Defendant Activity Rank
- Defendant Performance Rank
- Plaintiff Activity Rank
- Plaintiff Performance Rank
- Overall Success Rank
- Defendant Success Rank
- Plaintiff Success Rank
- Overall Success Score
- Defendant Success Score
- Plaintiff Success Score
- Overall Performance Score
- Defendant Performance Score
- Plaintiff Performance Score

Appendix E

Stats for Attorneys

See the attached Excel file for the stats related to the 864 ANDA attorneys. The spreadsheet covers the following information for each of the attorneys:

- Attorney name with a link to Patexia page
- Law firm with a link to Patexia page
- All Cases: Total number of ANDA cases for the period
- Defendant Cases
- Plaintiff Cases
- Overall Activity Rank
- Overall Performance Rank

- Defendant Activity Rank
- Defendant Performance Rank
- Plaintiff Activity Rank
- Plaintiff Performance Rank
- Overall Success Rank
- Defendant Success Rank
- Plaintiff Success Rank
- Overall Success Score
- Defendant Success Score
- Plaintiff Success Score
- Overall Performance Score
- Defendant Performance Score
- Plaintiff Performance Score

Appendix F

Stats for ANDA Attorneys

See the attached Excel file for the stats related to the 250 ANDA local counsel. The spreadsheet covers the following information for each of the attorneys:

- Attorney name with a link to Patexia page
- Law firm with a link to Patexia page

- Attorney's current city
- · Attorney's current state
- Overall Activity Rank
- Defendant Activity Rank
- Plaintiff Activity Rank
- All Cases
- Defendant Cases
- Plaintiff Cases

Appendix G

Stats for ANDA Judges

See the attached Excel file for the stats related to the 97 ANDA judges. The spreadsheet covers the following information for each of the attorneys:

- Judge's name
- Total cases
- Total patents in all cases
- Judge's score
- Plaintiff score
- Defendant score

Appendix H

Best Performing and Most Active Badges

As per our tradition, every year Patexia designs two categories of badges for Best Performing and Most Active Law Firms / Attorneys (Defendant, Plaintiff and overall). The badges are only provided to those

firms and attorneys who are ranked in the top 100 and choose to purchase the report (<u>Concierge Members</u> will automatically receive the badges if they are ranked among the top 100).



Contact Us

Founded in 2010 to bring efficiency and transparency to intellectual property by leveraging the power of data, technology and experts, Patexia is the largest network for IP professionals with over 80,000 IP attorney profiles. We offer IP services

under four distinct arms: Patexia Connect (recruiting), Patexia Contest (crowdsourcing), Patexia Expert (IP Due Diligence), and Patexia Insights (IP reports). Contact us today to learn more.

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Our Products

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